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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,045	12/18/2000	Jacques Bauer	GEI-084	6820
20311	7590	11/01/2004	EXAMINER	
MUSERLIAN, LUCAS AND MERCANTI, LLP			RUSSEL, JEFFREY E	
475 PARK AVENUE SOUTH			ART UNIT	PAPER NUMBER
15TH FLOOR				1654
NEW YORK, NY 10016				

DATE MAILED: 11/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

	Application No.	Applicant(s)
	09/720,045	BAUER ET AL.
	Examiner	Art Unit
	Jeffrey E. Russel	1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 01 October 2004.  
2a) This action is FINAL.                    2b) This action is non-final.  
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 34-53 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) Claim(s) \_\_\_\_\_ is/are allowed.  
6) Claim(s) 43-48 is/are rejected.  
7) Claim(s) 34-42 and 49-53 is/are objected to.  
8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.  
10) The drawing(s) filed on 05 February 2004 is/are: a) accepted or b) objected to by the Examiner.  
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:  
    1. Certified copies of the priority documents have been received.  
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
    Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
    Paper No(s)/Mail Date. \_\_\_\_\_  
5) Notice of Informal Patent Application (PTO-152)  
6) Other: \_\_\_\_\_

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1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 1, 2004 has been entered in part.

The amendment to the specification filed October 1, 2004 was not entered because it is not in proper amendment format under 37 CFR 1.121(b). The amendment to the specification did not include an amendment instruction which unambiguously identifies the location of the paragraph to be replaced. See 37 CFR 1.121(b)(1)(i). The amendment to the specification did not contain any markings, i.e. underlining and strike-through, which shows the subject matter to be added and the subject matter to be deleted. See 37 CFR 1.121(b)(1)(ii).

Because of the absence of any markings in the unentered amendment to the specification, the examiner did not review the amendment for the possible presence of new matter. It is recommended that Applicants specifically point out in their next response where the subject matter to be added to the specification is supported by the original disclosure of the invention. Statements such as those occurring in the second full paragraph of the Remarks are not particularly useful in identifying support for amendments to the specification.

It should be noted that although the third full paragraph of the Remarks refers to new claims 34 to 49, currently new claims 34-53 are pending in this application.

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However,

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this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reasons:

The Sequence Listing filed March 28, 2003 was not accompanied by a statement that the sequence listing includes no new matter. See 37 CFR 1.821(g).

Correction is required.

The statement filed February 5, 2004 does not satisfy the above requirement because it does not give any identifying data for the paper and computer readable forms. For example, the statement does not refer to the paper and computer readable forms filed March 28, 2003. Further, the statement that the "computer readable form diskette are identical" is unclear as to what is supposed to be identical to the computer readable form diskette.

The statement filed July 14, 2004 is identical to the one filed February 5, 2004, and therefore also does not satisfy the above requirement.

3. The disclosure is objected to because of the following informalities: There is no Brief Description of Figures 36-47 as required by 37 CFR 1.74. The amendment to the specification contained in the response filed February 5, 2004 refers only to Figures 1-35. Appropriate correction is required.

4. Claims 43-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 43, page 5 of the response filed October 1, 2004, line 8, recites a reactant comprising a  $(CH_2)_{q+1}COOH$  group which, after reaction with a reducing agent to yield the corresponding alcohol (see lines 10-11), is ultimately converted into an intermediate of formula (II) comprising a  $(CH_2)_qOH$  group (see line 16). However, if the  $(CH_2)_{q+1}COOH$  group is

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reduced to yield its corresponding alcohol, the corresponding alcohol will have  $q+2$  carbon atoms, not  $q$  carbon atoms as is indicated in line 16. It is believed that in the reactant formula at line 8, the subscript  $q+1$  should instead be  $q-1$ . Other references in the claims to, e.g., "position ( $q+1$ )", would have to be amended accordingly. If Applicants contend that the reactant formula at line 8 is correct, it is not clear what happens to the two additional carbon atoms present after the reduction step but not present in the intermediate of formula (II). This same issue arises in claim 44. Claim 43, at page 6, lines 11-12, recites a definition for X which conflicts with that given at claim 43, page 4, line 12, and page 5, lines 3-4. It is not clear which definition controls. The final product of the method of claim 43 comprises a -B-Y group. However, a -B-Y group is not present in the intermediate of formula (IV), and there is no mention of a reagent or reagents comprising B and/or Y groups in the method steps recited at page 6, lines 17-20. The alkylation, acylation, catalytic hydrogenation, and deprotection steps of page 6, lines 17-20, will not result in the introduction of a -B-Y group into the intermediate of formula (IV). It is not clear how the -B-Y group is to be introduced into the final product produced by the method of claim 43. Claim 44 is indefinite because the product to be produced as set forth in formula (I') in the preamble of the claim, is not the same as the product which is actually produced at the end of the claimed method (see page 9 of the response, lines 14-18). It is not clear which product is to be produced by the claimed method. Claim 44 is indefinite because it recites a definition of X at line 11 which contradicts the definition of X in the same claim at page 9, line 3. Claim 44 is indefinite because it defines R at page 9, lines 3-4, as being an alkyl or aryl group, whereas a broader definition of R is given at page 9, lines 8-9. It is not clear which definition is correct or is intended by Applicants.

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5. Claims 34-53 are objected to because of the following informalities: At claim 34, line 12, “carboxyalkyl[(C<sub>1-5</sub>)alkyl]” should be changed to “carboxy[(C<sub>1-5</sub>)alkyl]”. At claim 34, line 14, “phosphonoalkyl[(C<sub>1-5</sub>)alkyl]” should be changed to “phosphono[(C<sub>1-5</sub>)alkyl]”. At claim 34, line 15, “and” should be inserted after “hydroxysulfonyl” so that standard Markush terminology is used. At claim 36, line 4, the comma after “atoms’ should be deleted. It is not clear why Applicants are continually repeating definitions of variables in dependent claims 43 and 44. For example, in claim 43, the variables X and Y are defined at lines 12-24, again at page 6, lines 11-12, and a third time at page 7, 3-4. Multiple definitions of the same variables occur throughout claims 43 and 44. These definitions are in addition to the definitions found in the independent claim, and the definitions are not always consistent with one another (see, e.g., the additional limitation on R<sub>1</sub> or R<sub>2</sub> found at claim 43, line 9, where at least one is required to be an acyloxyacyl, and the additional limitation on X found at page 6, lines 11-12, where X is no longer permitted to be hydrogen). The repeated definitions of the same variables is at best redundant, and at worst leads to inconsistencies among the different definitions. At claim 43, line 20, “and” should be inserted after “hydroxysulfonyloxy[(C<sub>1-5</sub>)alkyl]” so that standard Markush terminology is used. At claim 43, page 5 of the amendment, line 8, if the compound formula is to be written in a single line rather than structurally, then “CHNH<sub>2</sub>” in the formula should be re-written as “CH(NH<sub>2</sub>)” so that it is clear how the amino group is to be attached to the remainder of the compound. At claim 43, page 5, last line through page 6, line 1, it is suggested that the phrase “selected from the group consisting of a  $\omega$ -hydroxy-amino acid, a  $\omega$ -amino-amino acid, and a  $\omega$ -thio-amino acid” be deleted. The phrase is at best redundant, and at worst is confusing because when X is an acid group, then the compound of formula (III) does not

comprise  $\omega$ -hydroxy,  $\omega$ -amino, or  $\omega$ -thio groups. In claims 45-48, line 1 of each claim, “process” should be changed to “method” so that terminology is consistent with that used in claim 43. Appropriate correction is required.

6. Claims 43, 44, and 49 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Independent claim 34 recites optional substituents for the R<sub>1</sub> and R<sub>2</sub> groups where the alkyl and carboxylic acids present in the optional substituents can only have from 1 to 24 carbon atoms (see claim 34, lines 6-9). However, when these optional substituents are recited in dependent claim 43, line 8, in dependent claim 44, line 8, or in dependent claim 49, line 8, no size limitations are set forth for the alkyl and carboxyl acids which can be present in the optional substituents. Accordingly, dependent claims 43 and 49 appear to be broader in scope than independent claim 34 with respect to the possible size of the optional substituents. Independent claim 34 recites eight specific possibilities for when X or Y is an acid group (see claim 34, lines 12-19). However, when X and Y are defined in dependent claim 49, page 11 of the response, line 1, no such limitation is present in the definition of X and Y. Accordingly, dependent claim 49 appears to be broader in scope than independent claim 34 with respect to the identities of the X and Y acid groups.

7. Claims 34-42 and 49-53 would be allowable if rewritten or amended to overcome the claim objections set forth in this Office action. Claims 43-48 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, and the claim objections set forth in this Office action.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

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JRussel

October 26, 2004